

**Maricopa Integrated Health Systems
Formulary Prior Auth Criteria**

Drug: Rebetron (Ribavirin oral capsule and interferon alfa-2b, recombinant injection)

Therapy:

Is indicated for the treatment of chronic hepatitis C in patients 18 years of age or older with compensated liver disease previously untreated with alpha interferon or who have relapsed following alpha interferon monotherapy

Inclusions:

- A) Diagnosis of Chronic Hepatitis C
- B) Detectable levels of hepatitis C virus (HCV) RNA (a viral load) in serum
- C) Signs of chronic hepatitis on liver biopsy
- D) Persistently elevated serum alanine aminotransferase (ALT) levels
- E) Standard hematologic test, liver function tests, thyroid stimulating hormone (TSH) and pregnancy test-prior and monthly (female)
- F) Patient has been Alcohol free for the last six months

Black box warning:

Is a pregnancy category X drug, and may cause birth defects. Therapy is contraindicated in women who are pregnant and in the male partners of women who are pregnant. Extreme care must be taken to avoid pregnancy during therapy and for 6 months after completion of treatment in female patients, and in female patients of male patients who are taking the combination.

Risk Factors/Contraindications:

- A) The primary toxicity of ribavirin is hemolytic anemia. A patient whose hg level falls below 8.5g/dl should be permanently discontinued from Rebetron therapy
- B) Severe psychiatric adverse events, including depression and suicidal behavior, have occurred during combination Rebetol/Intron therapy and with interferon alpha monotherapy, both in patients with or without psychiatric illness. **Should be used with extreme caution in patients with a history of preexisting psychiatric disorders who report a history of severe depression.** All patients should be monitored for evidenced of depression, and in severe cases, therapy should be stopped and psychiatric intervention sought.

Authorization:

Initially six months with re-authorization every six months with documented efficacy
Maximum of 24 week

Medical Director _____

Date _____